

# INTERNATIONAL SEARCH REPORT

International application No.

PCT/US04/19816

## A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : A61K 31/55, 31/445; A61F 13/02  
US CL : 424/448, 449; 514/183, 277, 319, 321

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)  
U.S. : 424/448, 449; 514/277, 183, 319, 321

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)  
STN, MEDLINE

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	WO 03/024456 A1 (EISAI CO., LTD.) 27 March 2003 (27.03.2003), page 5, lines 9-14; page 16-page 17; page 20.	1, 2, 6, 38, 39, 44 ----- 7, 31, 32
X --- Y	US 5,364,628 A (KISSEL et al) 15 November 1994 (15.11.1994), column 1, lines 60-66; column 2, lines 20-25, lines 42-65; column 5, lines 1-10; column 6, lines 45-65.	1, 6, 38 ----- 2, 7, 31, 32, 39, 44
X	US 4,916,132 (SEIBEL) 10 April 1990 (10.04.1990), see abstract.	1
A	US 6,383,471 B1 (CHEN et al) 7 May 2002 (07.05.2002), entire document.	1, 2, 6, 7, 31, 32, 38, 39, 44
A	BAYES et al. Gateways to Clinical Trials, Methods and Findings in Experimental and Clinical Pharmacology, July 2002, Vol. 24, No. 6, pages 371-391.	1, 2, 6, 7, 31, 32, 38, 39, 44

☐ Further documents are listed in the continuation of Box C.

☐ See patent family annex.

Special categories of cited documents:	
"A" document defining the general state of the art which is not considered to be of particular relevance	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"E" earlier application or patent published on or after the international filing date	"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"O" document referring to an oral disclosure, use, exhibition or other means	"&" document member of the same patent family
"P" document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search

05 March 2005 (05.03.2005)

Date of mailing of the international search report

06 JUN 2005

Name and mailing address of the ISA/US

Mail Stop PCT, Attn: ISA/US  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450

Facsimile No. (703) 305-3230

Authorized officer

Sreeni Padmanabhan  
Telephone No. 571-272-1600

*F. Roberts for*

# INTERNATIONAL SEARCH REPORT

International application No.

PCT/US04/19816

## Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:  
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☐ Claims Nos.:  
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☒ Claims Nos.: 3, 4, 5, 8 -30, 33-37, 40-43  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

## Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐  
☐

The additional search fees were accompanied by the applicant's protest.

No protest accompanied the payment of additional search fees.